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II. REMARKS

Claims 1 to 5, 7 to 9, 11 to 17, 19 to 37 and 51 to 84 are under examination.

A. Regarding the Amendments

Independent claims 1, 7, 13, 21, 26, 31, 51, 56, 61, 68, 73 and 78 have been amended to more clearly indicate that the claimed heparanase is pure enough to elicit anti-heparanase antibodies. The amendment is supported by the specification (as amended), for example, at page 19, lines 5-9, which disclose that "The recombinant protein may be useful in obtaining pure heparanase, which in turn may be useful in eliciting anti-heparanase antibodies, either poly or monoclonal antibodies."

Because the amendment to the specification and claims are fully supported, no issue of new matter arises.

B. Regarding the Enablement Rejection

Claims 51 to 84 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. More specifically, the Action alleges that a mere 90% homology with SEQ ID NO:1 encompasses more variants than can be routinely screened with a reasonable expectation of success. Further, the Action alleges that the specification does not provide adequate guidance with respect to the regions of the protein that may be modified without effecting activity. Applicant respectfully traverses the rejection.

In the previous response, Applicants introduced the decision of the Board of Patent Appeals and Interferences in *Ex Parte Sun*. In response, the Action states in conclusory fashion that "Applicants are reminded that the factors necessary for the determination of the enablement of the instant claims and that of the referred [sic]

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decision are different." **How they are different and why this difference makes a difference in finding enablement of the claims in Sun but not here are nowhere to be stated in the Action.**

Applicants respectfully remind the Examiner that in Sun a claim to 80% homology was found to be enabled. By contrast, only 90% homology is claimed here.

The Examiner takes the position that 90% homology with SEQ ID NO:1 encompasses more variants than can be routinely screened with a reasonable expectation of success. If this is true, why did the Board in Sun find that the variants encompassed by 80% homology to the WEE1 protein can be routinely screened with a reasonable expectation of success?

As discussed in the previous response, both the WEE1 protein in Sun the heparanase protein here have routine assays for screening. And, as discussed in the previous response, the declaration previously submitted in this case shows far more detailed guidance in modifying the heparanase protein of the subject invention that the guidance cited by the Board in Sun regarding the WEE1 protein.

In summary, the Board's decision in Sun dictates a finding of enablement here. If the Examiner disagrees with this assessment, Applicant is entitled to know precisely why this is not the case. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

C. Regarding the Written Description Rejection.

Claims 1 to 5, 7 to 9, 11 to 17, 19 to 37 and 51 to 84 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirements. Applicant respectfully traverses the rejection.

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The subject invention, as claimed, is directed to methods such as "A method of improving embryo implantation, the method comprising contacting an embryo with an effective amount of a purified recombinant heparanase." The specification, as amended, discloses that "The recombinant protein may be useful in obtaining pure heparanase, which in turn may be useful in eliciting anti-heparanase antibodies, either poly or monoclonal antibodies." See page 19, lines 5-9.

Given this disclosure, the skilled artisan would certainly understand that "the purified recombinant heparanase" recited in the method claims of the subject invention is pure enough to elicit anti-heparanase antibodies, as disclosed in the specification. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

D. Regarding the Obviousness Rejection.

Claims 1 to 5, 7 to 9, 11 to 17, 19 to 37 and 51 to 84 are rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Fuks et al., Gough et al. and Goshen et al. More specifically, the Action alleges that Fuks teaches that heparanase would be desirable in situations such as ovulation and transplantation; that Goshen teaches that embryo cytotrophoblasts express a heparanase resembling that of malignant cells, and that this enzyme is important in cell invasion associated with transplantation; and that Gough teaches methods for improving embryo transplantation by treating the embryos with LIF. The Action goes on to argue that the skilled artisan would have been motivated to practice the method of Gough by adding the heparanase of Fuks, given the teachings of Goshen. Applicant respectfully traverses the rejection.

While Applicant feels that the combination of all three references is not obvious and, in any event, is at best an invitation to try, to promote the prosecution of the subject application, Applicant has further amended the claims to require that the claimed heparanase be pure enough to elicit anti-heparanase antibodies. By contrast, the heparanase taught by Fuks could not elicit such antibodies. See Declaration of Iris

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Pecker (previously filed), paragraphs 5 and 6.

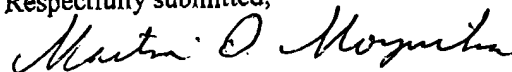
In the previous response, Applicant amended the claims to recite that the claimed heparanase "can" elicit such antibodies. The Examiner's position, however, is that the heparanase taught by Fuks "can" elicit such antibodies (even though it did not) because it is an inherent characteristic. As the Examiner knows, Applicant respectfully disagrees with this interpretation of the claims and has stated so for the record.

Nevertheless, to promote prosecution of the subject application, Applicant has further amended the claims herein. More specifically, the Action points out that Applicant's previous amendment does not require that the claimed heparanase be pure enough to elicit anti-heparanase antibodies. In response, Applicant has amended the claims to recite precisely this - "wherein said purified recombinant heparanase is pure enough to elicit anti-heparanase antibodies." Accordingly, Applicant respectfully requests that this rejection be withdrawn.

III. CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,



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Enclosed:
Petition for Extension (1 Month)
Request for Continued Examination (RCE)